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Fixed and dynamic health-related quality of life measurements

Abstract Measuring population health is important to evaluate the impact of interventions, to monitor the changes in health status, and to predict the need for health care. A number of tools have been developed to measure quality of life and health-related quality of life. According with the current taxonomy, the questionnaires may be classified as generic or specific, multi-dimensional or global. Recently, advances in the field of health outcome assessment have resulted in a new generation of approaches and measures that are based on a novel approach called dynamic health assessment. Through this approach,

subjects or patients answer only those questions relevant to their evaluation, in contrast to the fixed approach in which the number of questions is a priori determined. The dynamic headache impact test (HIT) that evaluates several dimensions such as ability to function on the job, at school, and in social situations, is presented and its value with respect to other fixed migraine-specific questionnaires is discussed.

Key words Quality of life • Health-related quality of life • Fixed and dynamic approaches • Migraine

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Quality of life is a complex and multidimensional concept that defines an individual's satisfaction or happiness with life in domains considered important. Often also referred to as "life satisfaction" or "subjective well-being", it is the broadest of all the concepts, where health is only one of the several dimensions of life usually considered in the models and taxonomies proposed so far [1–3].

Health-related quality of life (HRQOL) reflects an attempt to restrict the complex concept of quality of life to those aspects of life specifically related to a person's health that potentially respond to healthcare. The hub of the definition of HRQOL is considered the World Health Organization's definition of health "... as a state of complete physical, mental and social well-being, and not merely the absence of disease..." [4] that underlines the need to consider also subjective indicators to evaluate health, health sta-

tus and health outcomes [5, 6]. Most of the definitions of HRQOL include in their conceptualisation the domains of physical, mental, social functioning and well-being, as well as general health perceptions [7–9]. Among the several approaches and instruments available, most are questionnaires, psychometrically based [10, 11] and operationalised on a conceptualisation that is multidimensional, for which patients are the only source of information, reports and ratings. According with the current taxonomy [12, 13], the questionnaires now available may be classified as generic (including simple indicators, health profiles and utility measures) or specific (symptoms, diseases). Pros and cons of these instruments are briefly reported in Table 1 [14].

In the case of migraine, a chronic condition that has a well documented impact on the lives of those who suffer from it, as well as on families, employers and society, sev-

Table 1 Classification of measures of health-related quality of life (HRQOL) (modified from [14])

Approach	Strengths	Weaknesses
Generic	Single instrument Detects differential effects on different aspects of health status Comparisons across interventions and conditions possible	May not focus adequately on area of interest May not be responsive
Specific	Clinically sensitive May be more responsive	Doesn't allow cross-condition comparisons May be limited in terms of populations and interventions Restricted to domains of relevance to disease, population, function or problems Other domains important to HRQOL are not measured

Table 2 Dimensions measured by questionnaires developed specifically for migraine: migraine-specific quality of life (MSQ), headache disability index (HDI), migraine disability assessment (MIDAS), and headache impact questionnaire (HIMQ)

Dimensions	MSQ	HDI	MIDAS	HIMQ
Role functioning	✓	✓	✓	✓
Social functioning	✓	✓	✓	✓
Cognition	✓	✓		
Emotional distress	✓	✓		
Pain frequency and severity				✓
Energy or fatigue	✓			

eral HRQOL questionnaires have been used in clinical research and in clinical practice. An evaluation of the published articles [15–19] and of the quality of life instruments database [20] allows the identification of five instruments, one generic and four specific, that are more frequently used on migraine patients: SF-36 (short form 36 items), migraine specific QoL (MSQ) questionnaire, headache disability index (HDI), migraine disability assessment (MIDAS) questionnaire and headache impact questionnaire (HIMQ). The SF-36 [21] measures 8 multi-item scales (physical functioning; role functioning, physical; bodily pain; general health; vitality; social functioning; role functioning, emotional; and mental health); the dimensions measured by the four specific questionnaires are reported in Table 2. A total of 6 dimensions are considered – all questionnaires measure role and social functioning, only two measure cognition and emotional distress – whereas symptoms are rarely considered.

Recently, advances in the field of health outcome assessment have made available a new generation of approaches and measures, both specific and generic, that are based on a novel approach called *dynamic health assessment* [22, 23]. Details of this innovative approach are available elsewhere [15]. Briefly, using a computer-

adaptive test technology and measurement methods based on item response theory, from a large pool of items belonging to the most widely used health status surveys, only selected items relevant for the subject under evaluation are administered. Through this approach, subjects or patients answer only those questions relevant to their evaluation, in contrast to the *fixed approach* in which the number of questions is a priori determined. Accordingly, the advantages of this approach with respect to the corresponding fixed forms are:

- Brevity, in particular when only a few questions are necessary and selected, but at the same time accuracy, when a long form is needed,
- Direct comparability with scores of widely used measures,
- Lower data collection costs.

Moreover, the dynamic approach is supposed to have the same precision and interpretability and, when delivered as a Web-based survey, it allows immediate feedback reporting. At the moment several tools are available as Internet applications. Detailed information, examples and demos of a few generic and specific instruments for dynamic health assessment, specifically for headache, asthma, rhinitis, osteoarthritis, and congestive heart failure are available in the QalyMetric Web site [24].

In the DYNHA Headache Impact Test (HIT) [25], several dimensions are considered, such as the ability to function on the job, at school, and in social situations. Once the patient has responded to the selected items, two individualized reports are available. HIT was developed using items from four established measurement tools used successfully for years to measure the impact of headache; these tools are the specific questionnaires MSQ, HDI, HIMQ, and MIDAS. These items are included in a pool, and since DYNHA scores all responses on the same metric, results can be compared for those who answer different questions [15, 22]. As already mentioned, the HIT questionnaire does not have a fixed number of questions.

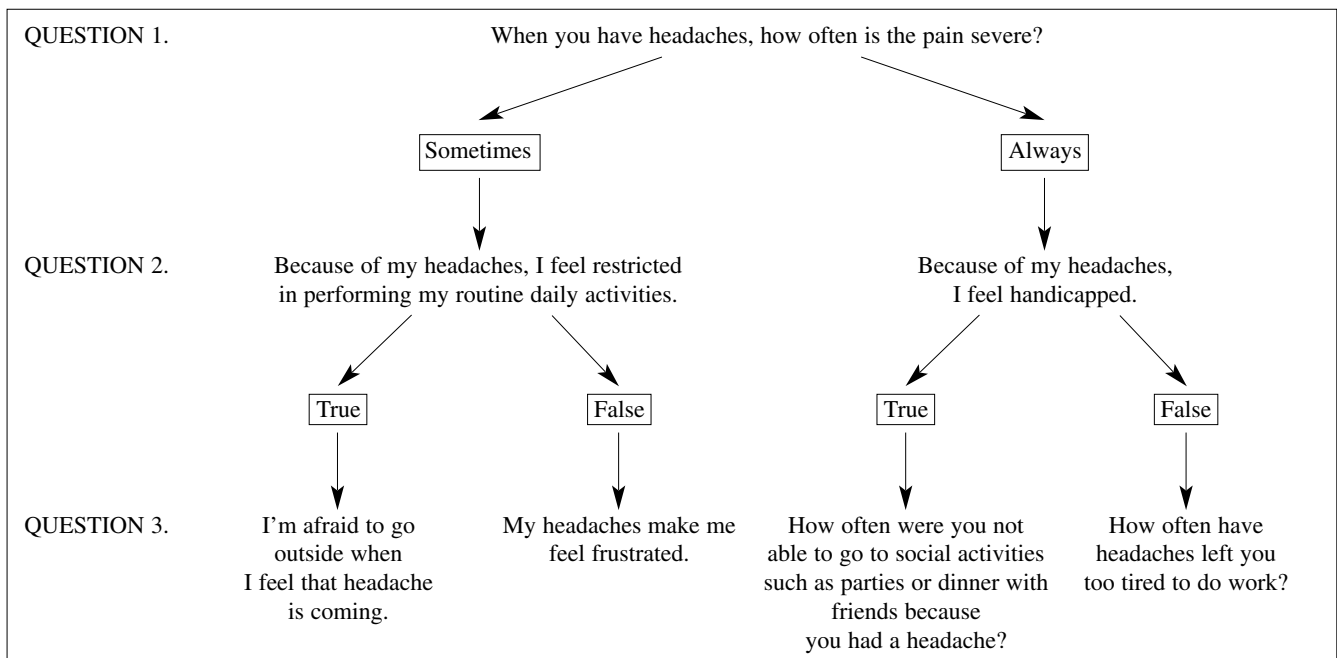


Fig. 1 Example of dynamic questioning used in the DYNHA Headache Impact Test as illustrated on the web site www.amIhealthy.com

Since fixed format questionnaires are less sensitive to some aspects of the impact of headache, improvements or aggravations in disability may not be captured in a disability profile. According to authors and copyright owners, HIT eliminates unnecessary questions, greatly reduces interviewing time and makes results comparable on a scale never before possible. Only a few minutes are generally required to complete the questionnaire and for this reason it's easy to administer to persons who are able to use a computer.

In Fig. 1, an example of this approach is shown [25]. The first question regards the severity of the pain, and depending on the answer, a second question is proposed. If the option *sometimes* is chosen, the second question regards the restrictions in performing routine daily activities; if the option *always* is chosen, the second question regards the sensation of being handicapped. In the same way, different questions are proposed on the basis of the answers to the second question.

Conclusions

Measuring population health is important to evaluate the impact of interventions, to monitor the change in health status, and to predict the need for health care. Interest in measuring qualitative aspects of life that are most closely related to health, health care and health policy has

increased in recent years. In addition to the traditional clinical measures, questionnaires describing patients' subjective health status now incorporate standardized measures, and several psychometric measures are available. Examples of the use of these tools in the literature suggest that they may have an important role in clinical studies and in the evaluation of samples of the general population.

Although a large body of empirical evidence is available about the validity and reliability of the HRQOL questionnaires so far available, evidence of the clinical added value of HRQOL data in addition to the traditional clinical endpoints allow a better selection of treatment regimes or help make decisions at the individual level? is still lacking. In addition, the field is still plagued by unsolved methodological and logistic problems that hamper the validity and generalizability of results from clinical studies, i.e. most studies suffer problems of low compliance, high missing rates and poor methods to minimize the bias introduced by incompletely compiled questionnaires. Guidelines to optimise the use of HRQOL in clinical studies were recently published [26] but are not yet fully implemented in most studies. For these reasons, regulatory agencies such as the US Food and Drug Administration and the European Medicines Evaluation Agency have a conservative and cautious attitude and, in general, do not recommend the use such measures in clinical studies for obtaining marketing approval [27].

Migraine is a condition that can be studied using subjective measures to evaluate the impact of disease and treatment on relevant aspect of patients' life and health, and that can be used to compare new, innovative tools with traditional measures. For these reasons, the dynamic approach is welcomed as a new tool that allows a relevant

reduction in respondent burden, thus increasing the study's feasibility and validity, but evidence about its incremental validity is still lacking. Comparative studies should be carried out in several diseases and conditions, and migraine can be considered an appropriate case-model.

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